D) AMENDMENTS TO THE DRAWINGS

None.

E) REMARKS

This Response is filed in response to the Office Action dated June 29, 2006.

Upon entry of this Amendment, claims 1-12, 14-19, 27 and 51 will be pending in the Application. Claims 13, 20-26 and 28-50 are canceled and claim 51 is added.

Claim 51 clarifies that the atmospheric conditions are obtained from personal flight data from the at least one subject.

In the outstanding Office Action, the Examiner maintained and made final the restriction requirement; rejected claims 1-50 under 35 U.S.C. 101 for double patenting; rejected claims 1, 2, 4 and 19 under 35 U.S.C. 102(b) as being anticipated by Mondry (U.S. Patent No. 5,682,877) hereinafter "Mondry"; rejected claim 15 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Mondry; rejected claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Mondry; rejected claims 3, 5, 6, 9 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Tripp Jr. et al. (U.S. H1039) hereinafter "Tripp"; rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Jones et al. (U.S. Patent No. 6,117,073) hereinafter "Jones"; rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Tripp, and further in view of Jones; rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Tripp, and further in view of Richardson (U.S. Patent No. 5,372,134) hereinafter "Richardson"; rejected claims 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Zysko (U.S. Patent No. 6,452,510) hereinafter "Zysko"; rejected claims 14 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Zysko, and further in view of Rapoport (U.S. Patent No. 6,488,634) hereinafter "Rapoport".

Rejection under 35 U.S.C. 102

The Examiner rejected claims 1, 2, 4 and 19 under 35 U.S.C. 102(b) as being anticipated by Mondry.

Specifically, the Examiner stated:

8. **As to Claim 1,** Mondry discloses a system for avoiding hypoxemia comprising an air source (388), a microprocessor (364) and a first sensor (362) to measure a physiological characteristic of the patient, wherein the microprocessor (364) determines the risk of hypoxemia related to predetermined values and creates a response to the physiological characteristic. (Please see Figure 9).

9. **As to Claim 2,** Mondry discloses the first sensor (362) to be a pulse oximeter and thus a sensor that detects the oxygen red cell saturation level of a patient. (Please see Figure 9).

10. **As to Claim 4,** Mondry discloses the system to be portable. (Please see Column 2, Lines 24-28)

11. **As to Claim 19,** Mondry discloses a system for avoiding hypoxemia that detects a first time reference and if the first time reference is exceeded by the second time reference emergency procedures are initiated. (Please see Column 4, Line 51 thru Column 5, Line 14).

Applicants respectfully traverse the rejection of claims 1, 2, 4 and 19 under 35 U.S.C. 102(b).

Mondry, as understood, is directed to a system for automatically selecting an appropriate oxygen dose to maintain a desired blood oxygen saturation level for patients having chronic obstructive lung disease or other patients requiring oxygenation or ventilation. The system delivers a first oxygen dose to the patient while repeatedly sequencing through available sequential oxygen doses at predetermined time intervals until the current blood oxygen saturation level of the patient attains the desired blood oxygen saturation level. The method then continues with delivering the selected oxygen dose to the patient so as to maintain the desired blood oxygen saturation level.

In contrast, independent claim 1 recites a system for avoiding hypoxemia in at least one subject exposed to a reduced atmospheric pressure, the system comprising an air source to supply an oxygen mixture to at least one subject; a microprocessor being configured to determine an increased risk of hypoxemia in the at least one subject and atmospheric conditions corresponding to hypoxemia in the at least one subject, the microprocessor activating the air source to provide the oxygen mixture to the at least one subject in response to a determination of

the increased risk of hypoxemia or atmospheric conditions corresponding to the increased risk of hypoxemia in the at least one subject; a first sensor to measure at least one physiological characteristic of the at least one subject, the first sensor transmitting a first signal to the microprocessor with the at least one physiological characteristic of the at least one subject; wherein the microprocessor determines the increased risk of hypoxemia in the at least one subject by comparing the at least one physiological characteristic of the at least one subject with a predetermined value for the at least one physiological characteristic of the at least one subject, the microprocessor determining the increased risk of hypoxemia in response to the at least one physiological characteristic of the at least one subject being less than the predetermined value for the at least one physiological characteristic. (Emphasis added).

The examiner is reminded that "'[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)." *See* Manual of Patent Examining Procedure, 8th Edition (MPEP), Section 2131.

In addition, "'[t]he identical invention must be shown in as complete detail as is contained in the ... claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)." *See* MPEP, Section 2131.

Several of the features recited by Applicant in independent claim 1are not taught or suggested by Mondry. First, Mondry does not teach or suggest a microprocessor being configured to determine an increased risk of hypoxemia in the at least one subject and atmospheric conditions corresponding to hypoxemia in the at least one subject as recited by Applicant in independent claim 1. Mondry uses a microprocessor to execute a control strategy to maintain oxygen saturation levels in a predetermined narrow range of acceptable values or at an acceptable discrete level. *See* col. 7, lines 54-58. The microprocessor of the present invention is configured to determine an increased risk of hypoxemia in the at least one subject and atmospheric conditions corresponding to hypoxemia in the at least one subject, the microprocessor activating the air source to provide the oxygen mixture to the at least one subject in response to a determination of the increased risk of hypoxemia or atmospheric conditions

corresponding to the increased risk of hypoxemia in the at least one subject. That is, in addition to providing oxygen when needed by the subject, i.e., in response to one physiological characteristic being less than a predetermined value, the microprocessor can also supply oxygen to a subject when atmospheric conditions correspond to an increased risk of hypoxemia. In other words, as disclosed on page 30 of paragraph [0072], even without a subject's blood oxygen content being considered hypoxemic, i.e., based solely upon the aircraft cabin reaching a pressure altitude of sufficient magnitude, the microprocessor can authorize oxygen to be supplied to a subject. This could occur as a result of either a gradual or even sudden loss of loss of cabin pressure, which corresponds to an increased risk of hypoxemia to the subject. In contrast, the microprocessor of Mondry does not have this claimed preventative safety feature, as Mondry only teaches providing oxygen after the patient's blood oxygen level drops sufficiently below a predetermined level. That is, the microprocessor in Mondry neither monitors atmospheric conditions corresponding to hypoxemia nor activates an air source in response to atmospheric conditions corresponding to an increased risk of hypoxemia. Thus, since Mondry does not teach or suggest all of the limitations recited in independent claim 1, Applicant respectfully submits that Mondry does not anticipate Applicant's invention as recited in independent claim 1.

Therefore, for the reasons given above, independent claim 1 is believed to be distinguishable from Mondry and therefore is not anticipated nor rendered obvious by Mondry.

Dependent claims 2, 4 and 19 are believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claims 2, 4 and 19 recite further limitations that distinguish over the applied art.

For example, in claim 19, Applicant respectfully disagrees that Mondry initiates emergency procedures in response to a patient not achieving a predetermined blood oxygen reading within a first predetermined time. While in such a circumstance, Mondry does disclose raising the oxygen concentration to the patient, Applicant asserts merely raising the oxygen concentration as not being an emergency procedure. However, even if raising the oxygen concentration can be considered an emergency procedure, which it isn't, Mondry does not teach or suggest the patient being required to perform an affirmative act to prevent initiation of the emergency procedures. In addition in Mondry, the patient is automatically provided a raised

oxygen concentration based on insufficient blood oxygen readings. The patient in Mondry cannot perform an affirmative act to prevent the provision of raised oxygen concentration.

In conclusion, it is respectfully submitted that claims 1, 2, 4 and 19 are not anticipated nor rendered obvious by Mondry and are therefore allowable.

Rejection under 35 U.S.C. 102 or 103

The Examiner rejected claim 15 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Mondry.

Specifically, the Examiner stated that

> 16. **As to Claim 15,** Mondry discloses a system for avoiding hypoxemia wherein the microprocessor is remote from the subject. As shown in Figure 9, the attachment of the device to the patient is via the patient's foot. Therefore it would have been obvious if not inherent for the device to be connected to the patient's foot via a wire for the purpose of attempting not to disturb the natural movement of the patient.

Applicant respectfully traverses the rejection of claim 15 under either 35 U.S.C. 102(b) or 35 U.S.C. 103(a).

The previous discussion of Mondry is also applicable here.

Dependent claim 15 is believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claim 15 recites further limitations that distinguish over the applied art.

Therefore, for the reasons given above, claim 15 is believed to be distinguishable from Mondry and therefore is not anticipated nor rendered obvious by Mondry.

Rejection under 35 U.S.C. 103

A. Claim 10 over Mondry

The Examiner rejected claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Mondry.

Specifically, the Examiner stated that

20. **As to Claim 10,** Mondry discloses the system to be portable. (Please see Column 2, Lines 24-28). Yet fails to expressly disclose the configuration of the device to be in one single unit. At the time the invention was made, the compact and portable design of devices for emergency use was well known for the purpose of providing efficient patient care. Therefore, it would have been obvious to one having ordinary skill in the art to design a system into a portable compact single unit as the Applicant has done. Moreover, Applicant has not asserted that the specific structural design of the system to avoid hypoxemia recited provides a particular advantage, solves a stated problem or serves a particular purpose different from that of providing a compact unit capable of aiding emergency personnel in providing fast and efficient patient care, thus the use of this compact unit lacks criticality in its design.

Applicant respectfully traverses the rejection of claim 10 under 35 U.S.C. 103(a).

The previous discussion of Mondry is also applicable here.

Dependent claim 10 is believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claim 10 recites further limitations that distinguish over the applied art.

For example, the Examiner concedes that Mondry does not disclose the device to be in one single unit. In addition, Applicant respectfully disagrees that the unit of the present invention lacks criticality in its compact design. As stated in paragraph [0073] of the present specification, "the safety system which is otherwise incorporated within a single portable container may be brought on board the aircraft for use during the flight and removed from the aircraft upon completion of the flight and may be further dedicated for the use of a particular passenger. In other words, the safety system may be a stand-alone system for individual use." There are strict limitations that apply to the size and weight of "carry on luggage" a passenger may bring on board the aircraft. Such restrictions are commonplace in modern commercial air travel. In addition, if desired, each passenger in a commercial plane could bring the system of the present invention into the aircraft. In order to accommodate this possibility, individually or collectively, as previously discussed, it is very important that the device be compact.

Therefore, for the reasons given above, claim 10 is believed to be distinguishable from Mondry and therefore is not anticipated nor rendered obvious by Mondry.

B. Claims 3, 5, 6, 9 and 27 over Mondry in view of Tripp

The Examiner rejected claims 3, 5, 6, 9 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Tripp.

Specifically, the Examiner stated that

22. **As to Claim 3,** Mondry discloses a system for avoiding hypoxemia that uses a baseline value to determine whether action is required by the doctor to assist the patient in additional oxygen ventilation; however, Mondry fails to teach the predetermined value for the oxygen red cell saturation level to be about 91 percent. However, the disclosed oxygen saturation level was known at the time the invention was made. Specifically Tripp teaches the effects of oxygen saturation depletion in patients and a desire to maintain oxygen saturation levels between 86 percent and 95 percent, if not higher, to avoid the distress caused by oxygen depletion. (Please see Column 10, Lines 33-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify system of Mondry to operate at values around 91 percent because it is well known in the art, as taught by Tripp, as a point in which the effects of oxygen depletion can be corrected prior to loss of cognitive mental ability or loss of consciousness.

23. **As to Claim 5,** Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-26). Yet Mondry fails to expressly disclose the use of the device in an aircraft. However the use of a system for avoiding hypoxemia was well known that the time the invention was made. Specifically Tripp discloses a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract) Therefore, it would have been obvious, if not inherent, to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft as taught by Tripp for the purpose of protecting the physiological well-being of the aircraft operator during flight.

24. Further, Examiner notes that Applicant has essential claimed a statement of intended use. Specifically, in **Claim 5,** Applicant recites "for use in an aircraft." The system of Mondry as modified by Tripp disclose an apparatus in which the claimed functional limitations can inherently be performed since the system of Mondry as

modified by Tripp is fully capable of being used in an aircraft. Thus, this recitation is a statement of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may not be recited either structurally or functionally, claims directed to an apparatus must be distinguished form the prior art of record in terms of structure rather than function alone. Please see MPEP §2114.

25. **As to Claim 6,** Mondry discloses a system for avoiding hypoxemia that detects a first time reference and if the first time reference is exceeded by the second time reference emergency procedures are initiated. (Please see Column 4, Line 51 thru Column 5, Line 14).

26. **As to Claim 9,** Mondry discloses a system comprising all the limitations recited in **Claim 9**, with the exception of the system to be used in an aircraft having an under pressurized cabin. However, the use of a system to avoid hypoxemia in an under pressurized cabin was well known at the time the invention was made. Specifically Tripp discloses a system that is used in high-performance tactical aircraft. As well known, the cabin pressures in tactical aircrafts decreases in relation to increases in altitude. The system of Tripp is to be used by the aircraft operator for the purpose of detecting the physiological well-being and detecting potential periods of blackout as a result of oxygen depletion. (Please see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft having an under pressurized cabin as taught by Tripp for the purpose of protecting the aircraft operator from the negative effects of oxygen depletion.

27. Further, Examiner notes that Applicant has essential claimed a statement of intended use. Specifically, in **Claim 9,** Applicant recites "for use in an aircraft having an under pressurized cabin." The system of Mondry as modified by Tripp disclose an apparatus in which the claimed functional limitations can inherently be performed since the system of Mondry as modified by Tripp is fully capable of being used in an aircraft. Thus, this recitation is a statement of intended use utilizing functional language, which may not be given patentable weight in apparatus claims. While features of an apparatus may not be recited either structurally or functionally, claims directed to an apparatus must be distinguished form the prior art of record in terms of structure rather than function alone. Please see MPEP §2114.

28. **As to Claim 27,** Mondry discloses a system for avoiding hypoxemia comprising an air source (368), a microprocessor (364) and a first sensor (362) to measure a physiological characteristic of the patient, wherein the microprocessor (364) determines the risk of hypoxemia related to predetermined values and creates a response to the physiological characteristic. (Please see Figure 9). Inherently the first sensor (362) is a pulse oximeter and thus a sensor that detects the oxygen red cell saturation level of a patient. Further, Mondry discloses a system for avoiding hypoxemia that uses a baseline value to determine whether action is required by the doctor to assist the patient in additional oxygen ventilation; however, Mondry fails to teach the predetermined value for the oxygen red cell saturation level to be about 91 percent. However, the disclosed

Applicant respectfully traverses the rejection of claims 3, 5, 6, 9 and 27 under 35 U.S.C. 103(a).

In contrast to Mondry and Tripp, independent claim 27 recites a system for avoiding hypoxemia in at least one subject exposed to a reduced atmospheric pressure, the system comprising: an air source to supply an oxygen mixture to at least one subject; a microprocessor being configured to determine an increased risk of hypoxemia in the at least one subject and atmospheric conditions corresponding to the increased risk of hypoxemia in the at least one subject and to control the air source to provide the oxygen mixture to the at least one subject in response to the determination of the increased risk of hypoxemia or atmospheric conditions corresponding to the increased risk of hypoxemia in the at least one subject; a pulse oximeter to measure at least one oxygen red cell saturation level for arterial circulation of the at least one subject, the pulse oximeter transmitting a first signal to the microprocessor with the at least one oxygen red cell saturation level for arterial circulation of the at least one subject; wherein the microprocessor determines the increased risk of hypoxemia in the at least one subject by comparing the at least one oxygen red cell saturation level for arterial circulation of the at least one subject with a predetermined value of about 91 percent for the at least one oxygen red cell saturation level for arterial circulation of the at least one subject, the microprocessor determining the increased risk of hypoxemia in response to the at least one oxygen red cell saturation level

for arterial circulation of the at least one subject being greater than the predetermined value for the at least one oxygen red cell saturation level for arterial circulation. (Emphasis added)

The previous discussion of Mondry is also applicable here.

Tripp, as understood, is directed to a monitoring system containing sensors in an oxygen mask portion of a tactical aircraft pilot or aircrew member. The sensors sense arterial blood supply during high positive G-force maneuvers that diminish blood flow to the cranial region of the pilot.

As discussed above, independent claim 1 is believed to be allowable over Mondry. For similar reasons for independent claim 27, as amended, Tripp fails to teach or discuss a microprocessor being configured to determine an increased risk of hypoxemia in the at least one subject and atmospheric conditions corresponding to hypoxemia in the at least one subject.

Dependent claims 3, 5, 6, 9 are believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claims 3, 5, 6, 9 recite further limitations that distinguish over the applied art.

For example, for claim 6, similar to claim 19, Applicant respectfully disagrees that Mondry initiates emergency procedures in response to a patient not achieving a predetermined blood oxygen reading within a first predetermined time. While in such a circumstance, Mondry does disclose raising the oxygen concentration to the patient, Applicant asserts merely raising the oxygen concentration as not being an emergency procedure. However, even if raising the oxygen concentration can be considered an emergency procedure, which it isn't, Mondry does not teach or suggest the patient being required to perform an affirmative act to prevent initiation of the emergency procedures. In addition in Mondry, the patient is automatically provided a raised oxygen concentration based on insufficient blood oxygen readings. The patient in Mondry cannot perform an affirmative act to prevent the provision of raised oxygen concentration. Therefore, Mondry fails to teach the claim limitation "the at least one subject being required to perform an affirmative act to reset to reset the first time reference."

Therefore, for the reasons given above, claims 3, 5, 6, 9 and 27 are believed to be distinguishable from Mondry and/or Tripp, and therefore are not anticipated nor rendered obvious by Mondry and/or Tripp.

C. Claims 17 and 18 over Mondry in view of Jones

The Examiner rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Jones.

Specifically, the Examiner stated that

> 32. **As to Claim 7,** Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in an aircraft and the transmission of an emergency message to an airport tower. Regarding the expressed disclosure of the device to be used in an aircraft, the use of a system for avoiding hypoxemia in an aircraft was well known that the time the invention was made. Specifically Tripp teaches a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Regarding the transmission of an emergency message, the use of a system to clinically diagnose a patient and transmit a signal to a dispatch unit was well known at the time the invention was made. Specifically Jones teaches a medical database system, which acquires and stores information about the patient. Further, this information is transmitted to a dispatch unit, which determines the care required for the patient. (Please see Column 4, Line 47 thru Column 5, Line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft and to send an emergency signal to a dispatch unit as well-being of the aircraft operator during flight and creating an efficient network to assist [1] in patient care.

Applicant respectfully traverses the rejection of claims 17 and 18 under 35 U.S.C. 103(a). The previous discussion of Mondry is also applicable here.

Jones, as understood is directed to an integrated medical database system for the emergency medical transportation business. The system includes different modules, i.e., dispatch, clinical, administration and billing, that can share information therebetween.

Dependent claims 17 and 18 are believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claims 17 and 18 recite further limitations that distinguish over the applied art.

It is the Examiner's position that it was well known at the time the invention was made to provide a device that provides a warning signal to a user, and that Jones discloses an audio and visual signal that is sent to the user when oxygen saturation levels have depleted for the purpose of advising the user to take action to increase oxygen saturation. First of all, Jones is directed to an integrated medical database system for the emergency medical transportation business. Any information provided in that context would not be provided to the user (patient), but to the medical professional for interpretation. Also, if this rejection is to be maintained, Applicant requests the Examiner point to the teachings relied upon to meet the limitation "discloses an audio and visual signal that is sent to the user when oxygen saturation levels have depleted for the purpose of advising the user to take action to increase oxygen saturation."

Therefore, for the reasons given above, claims 17 and 18 are believed to be distinguishable from Mondry and/or Jones, and, therefore are not anticipated nor rendered obvious by Mondry and/or Jones.

D. Claim 7 over Mondry in view of Tripp, and further in view of Jones

The Examiner rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Jones.

Specifically, the Examiner stated that

> 32. **As to Claim 7,** Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in an aircraft and the transmission of an emergency message to an airport tower. Regarding the expressed disclosure of the device to be used in an aircraft, the use of a system for avoiding hypoxemia in an aircraft was well known that the time the invention was made. Specifically Tripp teaches a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Regarding the transmission of an emergency message, the use of a system to clinically diagnose a

patient and transmit a signal to a dispatch unit was well known at the time the invention was made. Specifically Jones teaches a medical database system, which acquires and stores information about the patient. Further, this information is transmitted to a dispatch unit, which determines the care required for the patient. (Please see Column 4, Line 47 thru Column 5, Line 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Mondry for use in an aircraft and to send an emergency signal to a dispatch unit as taught by Tripp and Jones, respectively, for the purpose of protecting the physiological well-being of the aircraft operator during flight and creating an efficient network to assist in patient care.

Applicant respectfully traverses the rejection of claim 7 under 35 U.S.C. 103(a).

The previous discussion of Mondry and Jones are also applicable here.

Dependent claim 7 is believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claim 7 recites further limitations that distinguish over the applied art.

Therefore, for the reasons given above, claim 7 is believed to be distinguishable from Mondry and/or Jones, and therefore are not anticipated nor rendered obvious by Mondry and/or Jones.

E. Claim 8 over Mondry in view of Tripp, and further in view of Richardson

The Examiner rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Tripp, and further in view of Richardson.

Specifically, the Examiner stated that

34. **As to Claim 8,** Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet Mondry fails to expressly disclose the use of the device in aircraft and emergency procedures to include decreasing the aircraft altitude. Regarding the expressed disclosure of the device to be

used in an aircraft, the use of a system for avoiding hypoxemia in an aircraft was well known that the time the invention was made. Specifically Tripp teaches a system that is used in aircraft for the purpose of detecting potential periods of blackout by the aircraft operator due to instances of oxygen depletion. (Please see Abstract). Regarding the emergency procedures, the use of a system to disclose emergency procedures to including the decreased altitude of an aircraft were well known at the time the invention was made. Specifically Richardson teaches an aviation hypoxia monitor wherein a signal is sent to a "pilot to alert the patient to reduce his altitude or provide additional oxygen for the cockpit area" for the purpose of avoiding the troubles associated with oxygen depletion (Please see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system to reduce altitude as taught by Tripp and Richardson, respectively, for the purpose of protecting the physiological well-being of the aircraft operator during flight.

Applicant respectfully traverses the rejection of claim 8 under 35 U.S.C. 103(a).

The previous discussion of Mondry and Tripp are also applicable here.

Richardson, as understood, is directed to a hypoxia monitor incorporated into the headphones worn by a pilot. "The monitor provides a visual and audio signal if the blood level of the pilot decreases significantly. This will alert the pilot to either reduce his altitude or provide additional oxygen for the cockpit area." *See* Abstract.

Dependent claim 8 is believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claim 8, as amended recites further limitations that distinguish over the applied art.

For example, claim 8 has been clarified to recite that emergency procedures include automatically decreasing the aircraft altitude. Richardson teaches, "[o]nce the pilot is in the plane and the monitor is functioning, should the pilot's oxygen level reach a critical level, the alarm will sound alerting the potentially disoriented pilot and advise him by visual display to descend to a lower altitude or to add oxygen to the cockpit. This will enable the pilot to take corrective measures before a crash occurs." *See* col. 4, lines 24-30. In contrast, the present

invention discloses in paragraph [0071] that a pilot flying solo may be incapable of reducing altitude on his own, and that the system automatically reduce altitude on behalf of the pilot.

Therefore, for the reasons given above, claim 8 is believed to be distinguishable from Mondry and/or Richardson, and therefore are not anticipated nor rendered obvious by Mondry and/or Richardson.

F. Claims 11 and 12 over Mondry in view of Zysko

The Examiner rejected claim 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Zysko.

Specifically, the Examiner stated:

> 36. **As to Claims 11 and 12**, Mondry discloses a system for avoiding hypoxemia that is portable for the purpose of "allowing the treatment of patients outside the traditional hospital setting" (Please see Column 2, Lines 24-28). Yet fails to expressly disclose a second sensor to measure the atmospheric pressure ambient to the patient. However the use of a device for the measurement of ambient atmospheric pressure was well known at the time the invention was made. Specifically Zysko teaches the use of a device for the measurement of ambient atmospheric pressure in an airplane cabin for the purpose of determining the concentrations and other ambient conditions of the airplane cabin for the purpose of warning the user of low air pressure in the cabin which may result in incapacitation and damage to the nervous system and measures the pressure altitude in mean sea level. (Please see Column 1, Lines 25-40). Therefore, it would have been obvious to one having ordinary skill in the art to modify the teachings of Mondry to include a sensor for monitoring ambient atmospheric pressures, as taught by Zysko, for providing a warning to the user of potential situations of hypoxia.

Applicant respectfully traverses the rejection of claims 11 and 12 under 35 U.S.C. 103(a). The previous discussion of Mondry is also applicable here.

Zysko, as understood, is directed to a cabin pressure altitude monitor and warning system that provides a warning when a detected cabin pressure altitude has reached a predetermined level.

Dependent claims 11 and 12 are believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claims 11 and 12 recite further limitations that distinguish over the applied art.

Furthermore, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination." *See* Manual of Patent Examining Procedure, 8th Edition (MPEP), Section 2143.01.

The Examiner is reminded that "[i]f the proposed modification or combination of the prior art would change the principle or operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *See* MPEP, Section 2143.01.

> To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See Manual of Patent Examining Procedure, 8th Edition (MPEP), Section 2143.03.

It is the Examiner's position that it would have been obvious to modify the teachings of Mondry to include a sensor for monitoring ambient atmospheric pressures. However, Mondry is a self-contained system that monitors blood oxygen level of a patient while providing oxygen to the patient. As such, the purpose of Zysko, which is to alert of ambient atmospheric conditions for possible need of inspiring supplemental oxygen is absolutely redundant. In other words, one skilled in the art would have no reason to combine Mondry with Zysko, and the Examiner is only doing so after reviewing Applicant's invention, which is applying impermissible hindsight reasoning.

Therefore, for the reasons given above, claims 11 and 12 are believed to be distinguishable from Mondry and/or Zysko, and therefore are not anticipated nor rendered obvious by Mondry and/or Zysko.

G. Claims 14 and 16 over Mondry in view of Zysko, and in further view of Rapoport

The Examiner rejected claims 14 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Mondry in view of Zysko, and in further view of Rapoport.

Specifically, the Examiner stated:

> 38. **As to Claims 14 and 16,** the system of Mondry as modified by Zysko is discussed above yet fails to teach a physiological characteristic and atmospheric pressure on a storage device, transmitted to the microprocessor, and is compared to atmospheric environment of the patient. However, at the time the invention was made, the aforementioned device was well known. Specifically, Rapoport discloses an apparatus where in a patient is connected to a pulse oximeter and a pressure sensor. Prior to using the device, the patient's ambient pressure is measured and stored on the microprocessor (100). When the device is in use, additional values of the patient's airway pressures are monitored and analyzed for the purpose of determining if the patient is receiving the proper care. (Please see Figure 19 and Columns 13 and 14). As shown in Figure 19, the storage device is remote from the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the device of Mondy as modified by Zysko to further include the storage device as taught by Rapoport to provide an additional means of data to determine what treatment is needed during respiratory events.

Applicant respectfully traverses the rejection of claims 14 and 16 under 35 U.S.C. 103(a).

The previous discussion of Mondry and Zysko are also applicable here.

Rapoport, as understood, is directed to a system for treating sleep apnea by optimizing a controlled positive pressure to the airway of a patient to minimize the flow of air from a flow generator, ensuring that flow limitation in the patient's airway does not occur. The breathing apparatus consists of a flow generator, a flow sensor, an analog to digital converter, a microprocessor, a pressure controller, a patient supply hose and a nasal fitting. The microprocessor adjusts the air pressure in the patient supply hose when flow limitation is detected in the airway of the patient. *See* Abstract.

Dependent claims 14 and 16 are believed to be allowable as depending from what is believed to be allowable independent claim 1 for the reasons given above. In addition, claims 14 and 16 recite further limitations that distinguish over the applied art.

For example, Applicant notes that the pressure sensor in Rapoport, is used to measure the patient's positive breathing pressure, not a measurement of the atmospheric pressure surrounding the patient. (Emphasis added). Since a patient's lung pressure when not inhaling or exhaling is substantially equal to the surrounding atmospheric pressure, the pressure sensor measures only the relative pressure difference between the external atmospheric pressure and the pressure produced by the patient's respiration, not the absolute atmospheric pressure surrounding the patient. In addition, Figure 19 of Rapoport, which is a schematic, does not, by itself, show or suggest that a storage unit for recording data is remote from the patient. If the Examiner is to maintain this rejection, the Examiner is asked to point out in Rapoport where the pressure sensor measures atmospheric pressure outside of the context of the patient's positive breathing pressure, i.e., specifically records the atmospheric pressure surrounding the patient, and where in the specification the storage device is disclosed as being remote from the patient.

Double Patenting Rejection under 35 U.S.C. 101

The Examiner provisionally rejected claims 1-50 under 35 U.S.C. 101 as claiming the same invention as that of copending Application No. 10/419,672.

In response thereto, claims 20-26 are canceled in the present application, which claims will be the only pending claims in copending Application No. 10/419,672. Thus, there will be no overlapping claims with copending Application No. 10/419,672. In addition, added claim 51 has at least the distinctions provided for in the above discussion, and further depends on the existing claim 1. Therefore, Applicant submits that pending claims 1-12, 14-19, 27 and 51 comply with the provisions of 35 U.S.C. 101, and therefore are allowable.

CONCLUSION

In view of the above, Applicant respectfully requests reconsideration of the Application and withdrawal of the outstanding objections and rejections. As a result of the amendments and

remarks presented herein, Applicant respectfully submits that claims 1-12, 14-19, 27 and 51 are not anticipated by nor rendered obvious by Mondry, Tripp, Jones, Richardson, Zysko, Rapoport or their combination and thus, are in condition for allowance. As the claims are not anticipated by nor rendered obvious in view of the applied art, Applicant requests allowance of claims 1-12, 14-19, 27 and 51 in a timely manner. If the Examiner believes that prosecution of this Application could be expedited by a telephone conference, the Examiner is encouraged to contact the Applicant.

The Commissioner is hereby authorized to charge any additional fees and credit any overpayments to Deposit Account No. 50-1059.

Respectfully submitted,

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Dated: September 26, 2006